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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/035,708	03/05/1998	FRANK P. ZEMLAN	91830	5121

26874 7590 01/02/2002

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EXAMINER
HAYES, ROBERT CLINTON

ART UNIT	PAPER NUMBER
1647	28

DATE MAILED: 01/02/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/035,708	Zemlan et al
Examiner	**Art Unit**
Robert C. Hayes, Ph.D.	1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Oct 19, 2001* .

2a) ☒ This action is **FINAL.** 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-14, 17, 19-24, 26, 27, 29, and 31* is/are pending in the application.

4a) Of the above, claim(s) *1-13, 21, and 22* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *14, 17, 19, 20, 23, 24, 26, 27, 29, and 31* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims *1-14, 17, 19-24, 26, 27, 29, and 31* are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
18) ☐ Interview Summary (PTO-413) Paper No(s). _____
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

DETAILED ACTION

1. The amendment filed 10/19/01 has been entered.

2. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration remains defective because it is not signed.

3. The rejection of claims 14-15, 17-18, 23-27 & 29-30 under 35 U.S.C. 112, first paragraph, as containing new matter for the recitation, "fragments thereof" of Goedert's tau protein of SEQ ID NO:1, is withdrawn due to the amendment or cancellation of the claims.

4. The rejection of claims 14-15, 17-20, 23-27 & 29-31 under 35 U.S.C. § 112, second paragraph, as being indefinite and incomplete for reciting an incomplete method is withdrawn due to the amendment or cancellation of the claims.

5. The rejection of claims 17 & 24 under 35 U.S.C. § 112, second paragraph, as being indefinite for the recitation of "less than 50 kDa" is withdrawn due to the amendment of the claims.

6. Applicant's arguments filed 10/19/01 have been fully considered but they are not deemed to be persuasive.

7. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

8. Claims 14, 17, 19-20, 23-24, 26-27, 29 & 31 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

No proper antecedent basis nor conception within context of that disclosed within the specification at the time of filing the instant application is apparent for the generic recitation of "traumatic central nervous system injury", versus "traumatic pia-arachnoid injuries"; thereby, constituting new matter. Applicant is invited to state by page and line number where such basis exists.

No proper antecedent basis nor conception within context of that disclosed within the specification at the time of filing the instant application is apparent for the broader recitation of "in the range of about 30 to *about* 50 kDa", versus that disclosed on pages 4 or 5 of the specification, in which "to about 50 kDa" broadens the range to $\pm$ 5% of 50 kDa (i.e., as it relates

to claims 17 & 24). Note that the specification on pages 4-5 specifically contemplates "*less* than *50 kDa*"; thereby, constituting new matter.

9. Claims 14, 17, 19-20, 23-24, 26-27, 29 & 31 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite and incomplete for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is ambiguous what the recitation "in the form of an isoform of tau protein of SEQ ID NO:1" exactly entails, since the sole "isoform of tau" appears now to be only that of SEQ ID NO:1. In other words, are Applicants attempting to broaden what isoforms of tau are being claimed? It is suggested that the claims be amended to "raised against an axonally-derived protein [in the form of an isoform of], which is the tau protein of SEQ ID NO:1" should obviate this rejection, and prevent a new matter rejection from alternatively being made.

10. Claims 14, 17, 19-20, 23-24, 26-27, 29 & 31 stand rejected under 35 U.S.C. 102(b) as being anticipated by Vandermeeren et al (WO 94/13795), for the reasons made of record in Paper #s 12, 17 & 25, and as follows.

In contrast to Applicants' assertions on pages 4-5 of the response, Alzheimer's disease is still reasonably a "traumatic central nervous system injury" because the central nervous system basal forebrain cholinergic neurons, whose dysfunction and death characterize this disease state, are traumatized, by definition. Moreover, this disease state is reasonably "traumatic" to both the

Alzheimer's patient and their family; thereby, still structurally meeting all limitations of "(a) obtaining CSF..." and "(b) treating said sample of CSF with at least one monoclonal antibody...", etc., as recited in the claims, in which tau inherently is the "axonally-derived protein" of SEQ ID NO:1, and in which detection and comparison with control CSF is disclosed on pages 19-29. See also pages 1, 10, 11, 13, 15-16 and Figure 4. Lastly, again note that Vandermeeren et al. specifically disclose that tau "is abundantly present in the axonal compartment of these neurons".

Therefore, Applicants' arguments remain not persuasive.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (703) 305-3132. The examiner can normally be reached on Monday through Thursday, and alternate Fridays, from 8:30 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Robert C. Hayes, Ph.D.
December 17, 2001

GARY L. KUNZ
SUPERVISORY PATENT EXAMINER
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